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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Application Number: 10/702,194
Filing Date: November 04, 2003
Appellant(s): SOLOMON ET AL.

MAILED
MAY 04 2007
GROUP 3700

Tiffany Levato
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 26, 2007 appealing from the Office action mailed August 28, 2006.

(1) Real Party in Interest

The real party in interest is Aspiration Medical Technology LLC.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

Claims 1-15 and 20 are withdrawn from consideration as not directed to the elected invention.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: "III. Whether claims 17 and 18 are unpatentable under 35 U.S.C. 103 over Shapiro."

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Shapiro, Kenneth Joel "Animal Models of Human Psychology: Critique of Science, Ethics and Policy" (1998), pp. 113-210

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-18 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro.

With respect to **claim 17**: Shapiro teaches a method comprising: inserting a tube into a patient such that a proximal end portion of the tube is disposed in the upper digestive system of the patient and a distal end portion of the tube extends externally from the patient (Page 126, ¶1); connecting a pump in the form of a syringe to the distal end portion of the tube (Page 126, ¶1); controlling the pump (by virtue of operating said syringe, i.e. pushing the plunger) to remove partially digested food from the upper digestive system of the patient through the tube (Page 126, ¶1).

Shapiro does not explicitly teach monitoring a volume of the pumped food, however, since the very function of the sham-feeding method taught by Shapiro is to draw out ingested foodstuffs in such a way as to prevent nutrient absorption (Page 126, ¶2), it would be obvious to one of ordinary skill in the art to modify the method of Shapiro so as to include the step of monitoring a volume of the pumped food.

Shapiro also does not explicitly teach ending the pumping when the monitored volume exceeds preset parameters within a given time. However, the purpose of a preset parameter is to provide a value that sets a boundary on a physical situation, for example the monitored volume of food required to prevent nutrient absorption (Page 126, ¶2). Therefore it would be obvious to one of ordinary skill in the art to modify the method of Shapiro so as to add the step of ending pumping when the monitored volume exceeds preset parameters within a given time.

With respect to **claim 18**: Shapiro teaches that said method further comprises the step of transmitting the volume of the pumped food to a health care provider. This argument is based

upon Shapiro's teaching that a health care provider administers the sham-feeding process, including the pumping of said monitored volume, thus said volume of pumped food is transmitted to a health care provider via collection of said volume in the syringe which is operated by said provider.

With respect to **claim 32**: Shapiro teaches a method of treating obesity comprising the steps of:

(a) positioning a tube that passes through an obese patient's abdominal wall into an upper digestive system of the obese patient (Page 126, ¶1); (b) allowing the obese patient to ingest food (Page 126, ¶1);

(c) extracting the food from the upper digestive system of the obese patient through the tube after the obese patient has ingested the food (Page 126, ¶1). Shapiro teaches that the food that has been extracted in step (c) is not reintroduced into the obese patient. (Page 126, ¶1)

Shapiro does not explicitly teach repeating steps (b) and (c) until the patient is no longer obese, wherein the food that has been extracted in step (c) is not reintroduced into the obese patient. However, since Shapiro does teach that the method mimics the "eating-without-calories strategy of bulimia" (Page 127, ¶1) and the bingeing-purging process (Page 126, ¶2), wherein bulimia is simply a series of repetitions of the bingeing-purging process to achieve the eating-without-calories effect, it would be obvious to one of ordinary skill in the art to repeat steps (b) and (c) taught by Shapiro with a reasonable expectation of success.

With respect to **claim 33**: Shapiro teaches a method of treating obesity comprising the steps of:

(a) introducing a passageway into an obese patient's upper digestive system such that the passageway passes through the obese patient's abdominal wall (Page 126, ¶1); (b) allowing the obese patient to ingest food (Page 126, ¶1); (c) extracting the food from the upper digestive

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system of the obese patient through the passageway after the obese patient has ingested the food (Page 126, ¶1); Shapiro teaches that the food that has been extracted in step (c) is not reintroduced into the obese patient. (Page 126, ¶1)

Shapiro does not explicitly teach repeating steps (b) and (c) until the patient is no longer obese. However, since Shapiro does teach that the method mimics the "eating-without-calories strategy of bulimia" (Page 127, ¶1) and the bingeing-purging process (Page 126, ¶2), wherein bulimia is simply a series of repetitions of the bingeing-purging process to achieve the eating-without-calories effect, it would be obvious to one of ordinary skill in the art to repeat steps (b) and (c) taught by Shapiro with a reasonable expectation of success.

With respect to **claim 34**: Shapiro teaches a method of achieving weight loss in an obese person having a passageway into the obese person's upper digestive system that passes through the obese person's abdominal wall, the method comprising the steps of: (a) ingesting food (Page 126, ¶1);

(b) extracting the food from the upper digestive system of the obese person through the passageway after the food has been ingested (Page 126, ¶1). Shapiro teaches that the food that has been extracted in step (c) is not reintroduced into the obese patient. (Page 126, ¶1)

Shapiro does not explicitly teach repeating steps (a) and (b) until the patient is no longer obese. However, since Shapiro does teach that the method mimics the "eating-without-calories strategy of bulimia" (Page 127, ¶1) and the bingeing-purging process (Page 126, ¶2), wherein bulimia is simply a series of repetitions of the bingeing-purging process to achieve the eating-without-calories effect, it would be obvious to one of ordinary skill in the art to repeat steps (b) and (c) taught by Shapiro with a reasonable expectation of success.

(10) Response to Argument

Response to Arguments

Appellant's arguments, see Appeal Brief, filed January 26, 2007, page 6, with respect to the rejection of claims 32-34 under 35 U.S.C. 112 have been fully considered and are persuasive. The rejection has been withdrawn.

Appellant's arguments filed January 26, 2007, with respect to the rejection of claims 32-34 under 35 U.S.C. 112 have been fully considered but they are not persuasive. Appellant argues that the method steps taught by Shapiro are not the same as those steps claimed and thus the results are not inherently the same. The prior art of Shapiro either teaches explicitly or fairly suggests all of the steps of the claimed method. In response to appellant's argument that Shapiro teaches a method as a way to mimic bulimia and thus does not teach a method for treating an obese patient, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Appellant further argues that claims 32 and 33 positively recite an obese patient. Shapiro also recites an obese patient in that Shapiro draws a connection to obese and bulimic individuals through the common thread that they eat too much. Shapiro teaches an animal bulimia model. While the rat which is the subject of Shapiro's sham-feeding model may not be obese upon the first cycle of ingesting foodstuffs, the rat necessarily becomes obese prior to the drawing out of said foodstuffs, otherwise the method taught by Shapiro does not produce valid results as a mimicry of bulimia. Bulimics can also be considered obese upon bingeing in that they can either subsequently purge or not purge to rid the excess calories they have just consumed. Shapiro teaches that the purging treats and prevents continued obesity, which is

also the intent of the claimed method. The patient, rat or otherwise, will necessarily no longer be obese upon the repeated ingestion and extraction of foodstuffs in the method taught by Shapiro because the very function of the sham feeding method is to prevent nutrient absorption which cannot be physically isolated from caloric absorption.

Appellant further argues that the repeating step constitutes a time-related limitation that specifies how long the steps must be repeated. In response to appellant's argument that the references fail to show certain features of appellant's invention, it is noted that the features upon which appellant relies (i.e., time period for the ingesting and extracting steps and thus also the repeating step) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). While in a broad sense this argument is correct, there is absolutely no claimed time interval for any of the steps that are repeated.

With respect to appellant's arguments regarding the rejection of claims 17 and 18: As an initial matter, claims 17 and 18 are rejected over Shapiro alone, not in view of Corley. Corley is merely provided as evidence that the step of transmitting the extracted volume to a healthcare provider is known. With respect to claim 17, appellant argues that the claimed monitoring step is not rendered unpatentable by Shapiro because ending pumping when pump capacity is exceeded is not the same as ending pumping when a preset parameter for the monitored volume has been reached. While this is true, appellant is reminded of the claim language which merely sets forth a preset parameter for the monitored volume. This parameter could in fact be the capacity of the pump or the volume or caloric value desired for the monitored volume. Ending the pumping once that parameter has been reached is also suggested by Shapiro, as Shapiro teaches that the sham feeding method prevents nutrient absorption. The continued

operation of the pump after this parameter (amount of nutrient absorbed) has been reached would nullify the function of the sham-feeding method. Appellant's further arguments with regard to Corely are not addressed herein as Corley was not used as a reference in the grounds of rejection of claims 17 and 18. With respect to claim 18, appellant's argument is moot in view of a restatement of the rejection of claim 18 in which it is stated that Shapiro does in fact explicitly teach transmitting the volume of food to a healthcare provider, as it is a healthcare provider that performs the sham-feeding process and operates the syringe (pump) that collects the monitored volume.

With respect to appellant's arguments regarding the rejection of claims 32-34: Appellant argues that Shpairo does not link bulimia to obesity as regards the operation of the sham feeding method. Examiner refers appellant to page 125, paragraph 1 of Shapiro in which Shapiro draws a clear link between obesity and bulimia that directly pertains to the sham feeding method, i.e. that the conditions of obesity and bulimia different only in that a bulimic purges after a bingeing incident, whereas the obese individual does not. The bingeing-purgeing effect is exactly mimicked by the sham feeding method and thus can also clearly be used on an obese individual to treat obesity, as the purging is the manner in which a bulimic "treats" his/her bingeing to prevent weight gain. Appellant's citation in support of appellant's argument on page 144 of Shapiro is taken entirely out of context by appellant and is not a mocking of the use of animal research at all. Shapiro is merely paraphrasing the viewpoint of an animal protectionist's ethical objections to animal research, which are merely opinions and certainly cannot be cited as a teaching by Shapiro as valid support of appellant's argument. Appellant further argues with respect to claims 32-34 that the recitation of an obese patient is "significant". Examiner has addressed similar arguments with respect to claims 17 and 18 *supra*. As to appellant's arguments regarding the case law of Perricone, the use of the method of Shapiro to treat

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obesity is not "a new use of an old product". Shapiro links obesity and bulimia and certainly fairly suggests the use of the sham feeding method to treat obesity. In *Perricone*, the issue lied in the prior art, which generally taught topical application, and so a claim directed to application to a skin sunburn would be considered a new use of an old product as it was never taught or fairly suggested by the prior art relied upon an evidence in the case. The instant application and the prior art of Shapiro do not present a similar situation to *Perricone* and thus that case law is not relevant.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

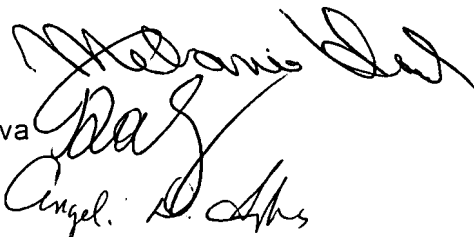
Melanie J. Hand

Conferees:

Melanie J. Hand

Tatyana Zalukaeva

Angela Sykes

Handwritten signatures of the three conferees. The signature for Melanie J. Hand is at the top, followed by Tatyana Zalukaeva's signature, and Angela Sykes' signature at the bottom. The signatures are written in black ink and are somewhat stylized.